

Congress of the United States
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October 28, 2003

The Honorable Bill Thomas
Chairman, Committee on Ways and Means
U.S. House of Representatives
1102 Longworth House Office Building
Washington, DC 20515

The Honorable Charles E. Grassley
Chairman, Committee on Finance
U.S. Senate
219 Dirksen Building
Washington, DC 20510

Dear Chairmen Thomas and Grassley:

As the Medicare conference enters its final weeks, we are writing to reiterate our views about the form of importation language that we recommend be included in the Conference Report. We believe that modeling the language on the suggestions below would significantly increase the Medicare bill's chance of passage by incorporating essential cost containment mechanisms into the bill.

The American people know that H.R. 1 and S. 1, as passed, do little to address the issue of skyrocketing drug costs. A recent USA TODAY/CNN/Gallup poll found that only 20 percent of Americans believe that the Medicare bills being debated would help their situation, with 69 percent believing their situation would remain the same or worsen. The same poll showed that only 19 percent of Americans believe that the bills would do enough to lower their drug costs.

Americans also know that opening prescription drug markets and allowing for the importation of FDA-approved drugs from FDA-approved facilities in other countries would significantly lower drug prices. In recent polling, more than two thirds of Americans consistently say they are in favor of drug importation.

Passing a drug benefit without cost containment mechanisms does a disservice to America's seniors and to all American taxpayers. Meaningful importation provisions could increase the value of the drug benefit while reducing the taxpayers' burden. With this in mind, we offer the following guidelines for the reimportation language that we recommend for Medicare prescription drug legislation. We believe that addressing the four areas outlined below would help to ensure that the provisions included in the final bill would be effective.

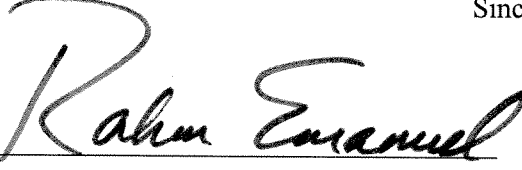

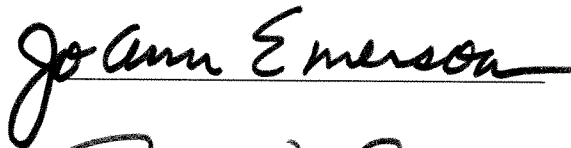
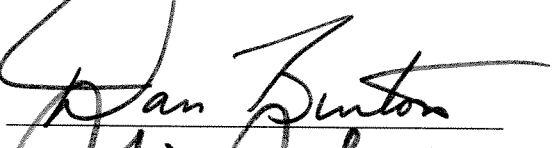
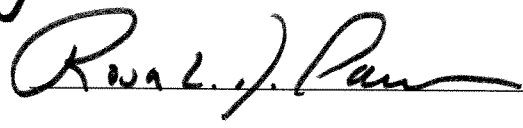
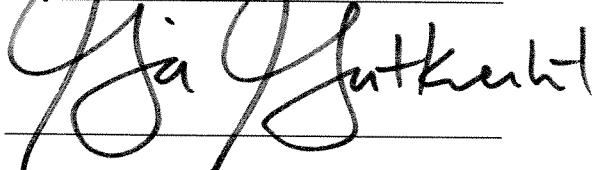
- **No "Poison Pill" Certification:** The most obvious danger to effective market access provisions would be inclusion of the so-called "certification" language contained in the 2000 Medicine Equity and Drug Safety Act. It is well known that this language creates an unattainable requirement. The fact that no such similar certification requirement has been imposed on any other trade bill or imported product betrays its true purpose – to guarantee the law is never implemented.
- **Prevention of Supply Manipulation:** Pharmaceutical manufacturers are already imposing supply restrictions in an attempt to thwart Americans' importation from Canada. In order to prevent this type of market-distorting conduct on the part of the drug companies, it is necessary to take at least one of the following approaches:

1. Broad-Based Market Access: The first approach to prevent supply manipulation is to allow American consumers access to prescription drugs in multiple markets so that it becomes impossible for the drug companies to effectively limit supplies or to prevent medicines from coming into the United States.
 2. Anti-discrimination Language: The second approach to combating supply manipulation is to prohibit it under federal law. The inclusion of language prohibiting discrimination is especially important if the Conference decides to limit market access legislation to Canada, since the relatively small size of Canada's market makes it susceptible to manipulations of supply.
- **Labeling Authorization**: In order that products imported into the United States can be labeled in accordance with FDA standards, the final legislation should provide – as the Senate Medicare bill already does – that importers have the right to reproduce at no additional cost the FDA-approved labeling for a product being imported into the United States.
 - **No Sunset Provision**: Including a sunset provision would cause uncertainty among the various parties who would be expected to make the investments needed to make a market access system work. Though Congress could amend or repeal the provision in the future if warranted, a sunset provision undermines the cost-saving potential of importation because it discourages the up-front infrastructural investment needed to implement the system.

In closing, we again wish to offer ourselves and our staffs as a resource during your consideration of the critically important issue of allowing Americans to access safe and affordable medicines from abroad.

There is overwhelming support across the nation for enacting market access provisions into law. We have all heard the voices of our constituents, in town hall meetings we have organized throughout the country and in letters and phone calls we receive daily, in support of our effort to ensure affordable drugs for all Americans. We look forward to working with you to accomplish this goal.

Sincerely,

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cc: House and Senate Conferees to H.R. 1 and S. 1.